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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN BARTHELOW CLASSEN

Appeal 2009-004501
Application 10/081,705
Technology Center 2100

Before JAMES D. THOMAS, CAROLYN D. THOMAS, and STEPHEN C. SIU, *Administrative Patent Judges.*

SIU, *Administrative Patent Judge.*

DECISION ON APPEAL[1]

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

This is a decision on appeal under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 250-300. Claims 1-249 are canceled. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

Invention

The invention relates to methods of screening for previously unrecognized adverse events associated with the use of a product or device (Spec. 3, ll. 8-9).

Independent claim 250 is illustrative:

> 250. A proprietary method of use for a product of manufacture or device, wherein the use was established according to the steps comprising:
>
> accessing one or more data sources, wherein at least one data source comprises adverse event data;
>
> analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device;
>
> identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, and then responsive to identifying of the essential adverse event, identifying the at least one previously unreported method of use for the product or device;
>
> documenting inventorship of the at least one method of use for the product or device; and

creating a database of proprietary essential adverse event information, the database storing data regarding the at least one essential adverse event,

wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, and

wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof.

References

The Examiner relies upon the following references as evidence in support of the rejection:

Jacob	US 3,885,566	May 27, 1975
Colombo	US 5,678,234	Oct. 14, 1997
Rivette	US 5,991,751	Nov. 23, 1999
Risen	US 6,018,714	Jan. 25, 2000
Stanton	US 2002/0039990 A1	Apr. 4, 2002 (filed Dec. 7, 2000)
D'Ambra	US 6,458,958 B1	Oct. 1, 2002 (filed Aug. 9, 2000)

Appellant's disclosed prior art, Spec. 7, ll. 15-26 ("ADPA").

Rejection

Claims 250, 256, 257, 270, 272, 274-276, 281, 285, 287, and 292-298 are rejected under 35 U.S.C. § 103(a) as being unpatentable over ADPA, Stanton, Rivette, and D'Ambra.

Claims 251, 252, 254, 258, 282[2], 286, 288, and 289 are rejected under 35 U.S.C. § 103(a) as being unpatentable over ADPA, Stanton, Rivette, D'Ambra, and Colombo.

Claims 253, 255, 259[3], 262, 263, 265, 267, 269, 271, 273, 279, and 290 are rejected under 35 U.S.C. § 103(a) as being unpatentable over ADPA, Stanton, Rivette, D'Ambra, Colombo, and Risen.

Claims 260, 261, 264, 266, 268, 277, 278, 280, 283, 284, and 291 are rejected under 35 U.S.C. § 103(a) as being unpatentable over ADPA, Stanton, Rivette, D'Ambra, and Risen.

Claims 299 and 300 are rejected under 35 U.S.C. § 103(a) as being unpatentable over ADPA, Stanton, Rivette, D'Ambra, and Jacob.

ISSUES

Issue 1

Appellant argues that the Stanton reference "offers neither a written description, nor a printed publication BEFORE the earliest effective filing date of Applicant's invention" (App. Br. 13).

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[2] In rejecting parent claim 252, the Examiner uses Colombo (Ans. 8); but, Colombo is not listed as part of the claim 282 rejection (Ans. 3-4). We discovered similar oversights in the Examiner's rejections of claims 259, 260-269, 271, 273, 277-280, 283, 284, 286, 288-291, 299, and 300. Appellant does not make any arguments based on these oversights. We therefore hold these oversights harmless.

[3] The Examiner further relies on the taking of official notice of facts in rejecting claims 259-269, 277, 283, 284, and 291, as well as claims 271, 278-280, and 290 which depend therefrom.

Issue: Did the Examiner err in using the Stanton reference in rejecting Appellant's claims?

Issue 2

Appellant argues that the "invention *expressly* excludes pharmo-genetics/pharmacogenomics" (App. Br. 14).

The Examiner finds that "the features upon which application relies . . . are not recited" (Ans. 13).

Issue: Did the Examiner err in finding that the claimed invention does not recite limitations argued by Appellant?

Issue 3

Appellant argues that "Stanton makes no requirement that the 'adverse event' MUST be 'new' or 'novel' or 'previously unreported' or unknown" (App. Br. 15).

Issue: Did the Examiner err in finding that ADPA, Stanton, Rivette, and D'Ambra would have taught or suggested identifying at least one previously unreported essential adverse event?

Issue 4

Appellant argues that "Rivette fails to teach or even mention creating a 'database of proprietary essential adverse event data'" (App. Br. 16).

Issue: Did the Examiner err in finding that ADPA, Stanton, Rivette, and D'Ambra would have taught or suggested creating a database of proprietary essential adverse event information, wherein the database comprises at least one of: a patent, a patent application, or patent publication?

Issue 5

Appellant argues that "the combination of Stanton, Rivette, and D'Ambra does not allow a 'predictable use of the prior art elements according to their established function'" (App. Br. 17).

Issue: Did the Examiner err in finding that it would have been obvious to an artisan to combine the teachings and suggestions of ADPA, Stanton, Rivette, and D'Ambra?

Issue 6

Appellant argues that claims 251, 252, and 254 "relate to determining the 'value of commercialization'" (App. Br. 18).

Issue: Did the Examiner err in finding that ADPA, Stanton, Rivette, D'Ambra, and Colombo would have taught or suggested determining the value of commercializing at least one use for a product of manufacture or device?

Issue 7

Appellant argues that "the rejection of Applicant's claims . . . supplemented with Official Notice taken of facts unsupported by documentary evidence[] is improper and should be reversed" (App. Br. 21).

Issue: Did the Examiner improperly take official notice of the state of the art?

Issue 8

Appellant argues that "Jacob fails to teach printed product warning information in conjunction with a 'proprietary method of use" (App. Br. 22).

Issue: Did the Examiner err in finding that ADPA, Stanton, Rivette, D'Ambra, and Jacob would have taught or suggested a proprietary method of use comprising providing printed product safety information in connection with product packaging?

Issue 9

Appellant argues that "evidence in the attached sworn Declaration of Dr. John B. Classen . . . demonstrates the ultimate evidence of nonobvious[ness] by offering real world evidence of copying and infringement of Applicant's claimed invention by another, and evidence of that third party's commercial success using Applicant's invention despite expressed skepticism by experts" (App. Br. 23).

Issue: Do secondary considerations of nonobviousness demonstrate that the Examiner erred in finding that the prior art would have taught or suggested the claimed invention?

FINDINGS OF FACT

The following Findings of Fact (FF) are shown by a preponderance of the evidence.

1. The Specification, under "BACKGROUND OF THE INVENTION," references U.S. Patent Application No. 09/804,289 (now U.S. Patent No. 6,584,472) (p. 1, ll. 14-20).
2. The Specification discloses that

> a new essential adverse event can mean a newly discovered adverse reaction such as the discovery of an increased rate of seizures associated with a drug, improved information such as [a] more accurate

> calculation of the rates of seizures in a group or subgroup, or the discovery of an increased rate of seizures in patients taking the drug along with one or more additional drugs.

(p. 12, l. 30 – p. 13, l. 3).

3. The Specification discloses that "[t]he final determination of what is 'essential' information is determined by a regulatory agency such as the FDA [Food and Drug Administration]" (p. 23, ll. 2-3).
4. The Specification discloses under the heading "Methods of Screening Adverse Events For Commercial Value" that "[a]ll essential adverse event information is not of equal value. Value depends on the potential value of making a generic product or device into a proprietary product or device" (p. 28, ll. 3-5).
5. ADPA discloses that "[b]ecause of the large volume of data that they contain, preferred adverse event database may include those of insurance companies, managed care organizations, pharmaceutical and medical device manufacturers and/or distributors, public health departments, hospitals and the like" (Spec. 7, ll. 15-18).
6. Stanton discloses

> correlating one or more variances in one or more genes in a plurality of patients with response [*sic*] to a treatment or a method of administration of a treatment. . . . The variances may be previously known to exist or may also be determined in the present method or combinations of prior information and newly determined information may be used. . . . Such

> information is useful, for example, for . . . demonstrating that a group of patients exists for which the treatment or method of treatment would be particularly beneficial or contra-indicated. Such demonstration can be beneficial, for example, for obtaining government regulatory approval for a new drug or a new use of a drug.

(¶ [0053]).

7. Stanton discloses that "[a]ll relevant demographic and historical data regarding patient drug response will be recorded in an anonymized database" (¶ [0831]).
8. Rivette discloses "databases of patents" (abstract).
9. Colombo discloses that "[m]odified sulfur cement was developed employing readily available and relatively inexpensive chemical modifiers which significantly improved product durability" (col. 3, ll. 62-65).
10. Jacob discloses that "[a] warning will soon be mandatory on the label of such disposable diapers stating that 'the backing (meaning the release paper strip in the context of this Specification) on the pull tabs should be disposed of properly to protect against infants ingesting or choking on them'" (col. 1, ll. 47-52).
11. The John Barthelow Classen declaration discloses that "I believe that my interaction with Elan Pharmaceuticals, is evidence of non-obviousness of my invention, demonstrating unexpectedness

and superiority of outcome over the prior art, evidence of commercial success, and evidence of copying" (p. 2).

12. The John Barthelow Classen declaration discloses that "[t]he '102 [6,683,102] patent is, in fact, the subject of my patent infringement suit with Elan. The Elan patents cover an adverse event . . . that is specifically covered by my '674 [6,219,674] patent" (p. 3).

13. The John Barthelow Classen declaration discloses that

> generic drug competitors have begun copying my technique in the hope of forcing Elan and King to cross-license the patents based on claims relating to the discovered drug/food interaction. Mutual Pharmaceutical Company, a generic manufacturer, has received its own patent . . . resulting from an identified drug/food interaction.

(p. 4).

14. The John Barthelow Classen declaration discloses that "[i]t was believed at the filing date of my '674 patent [Nov. 24, 1999] that it was not possible to completely prevent generic drug competition for the original formulation and original indication of a compound after the original patents had expired" (p. 6).

PRINCIPLES OF LAW

Claim interpretation

"In the patentability context, claims are to be given their broadest reasonable interpretations. . . . [L]imitations are not to be read into the claims from the specification." *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed.

Cir. 1993) (citations omitted). A claim meaning is reasonable if one of ordinary skill in the art would understand the claim, read in light of the specification, to encompass the meaning. *See In re American Academy of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998).

Obviousness

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, and (3) the level of skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results," *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007), especially if the combination would not be "uniquely challenging or difficult for one of ordinary skill in the art," *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (citing KSR, 550 U.S. at 418).

Secondary considerations, in the form of objective evidence such as commercial success, long felt but unresolved need, failure of others, and copying must be considered when present. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 960 (Fed. Cir. 1986). "It can be the

most probative evidence of nonobviousness in the record, and enables the [one] to avert the trap of hindsight." *Id.* Secondary considerations, such as unexpected results, must be established by factual evidence; mere argument or conclusory statements are insufficient. *Cf. In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984).

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). References may include published patent applications that were filed by another before invention by the applicant for patent. *See* 35 U.S.C. §§ 102(e)(1), 103(a); *cf. In re Giacomini*, 2010 WL 2674461, *1 (Fed. Cir. 2010) (a "patent has a patent-defeating effect as of the filing date of the provisional application to which it claims priority").

ANALYSIS

Issue 1

Appellant challenges the Examiner's use of the Stanton reference based on the publication date of Stanton and filing date of Appellant's application. Appellant claims the benefit of U.S. Provisional Application No. 60/270,697, filed February 22, 2001 (Spec. 1, ll. 12-13). Stanton was filed December 7, 2000. It is irrelevant that Stanton was published after

Appellant filed the present application. The patent-defeating effect of a published patent application is based on the published patent application's filing date, not its publication date. *See* 35 U.S.C. §§ 102(e)(1), 103(a); c*f. Giacomini*, 2010 WL 2674461 at *1.

For at least these reasons, we find no evidence persuasive of error in the Examiner's 35 U.S.C. § 103(a) rejection of claim 250-300 with respect to this issue.

Issue 2

Appellant argues that the references relate to technologies that fall outside the scope of the claimed invention. The Examiner finds that Appellant relies on features that are not found in the claim limitations. Based on Appellant's arguments in the Appeal Brief, we will decide the appeal of claims 250-300 with respect to issue 2 on the basis of claims 250 and 253. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellant submits that the Examiner errs in relying on Stanton because the Specification discloses that "the present invention is not intended to encompass pharmacogenomic techniques for screening" (App. Br. 13-14). However, Appellant fails to identify any claim recitation that limits the scope of the claimed invention to non-pharmacogenomic screening techniques. Appellant argues that "according to Applicant's invention there is *no clinical trial required*, nor does such a trial provide the necessary warning(s)" (App. Br. 15). Similarly, Appellant submits that "Stanton requires a gene database as a critical element of the invention, which element [*sic*] is expressly excluded from Applicant's invention" (App.

Br. 16) (citation omitted). But Appellant fails to identify any claim recitations that preclude a clinical trial or a gene database. Furthermore, the claim uses the open-ended "comprising" transitional phrase. Therefore, we find no error in the Examiner's reliance on Stanton.

Appellant argues that "D'Ambra never teaches to discover new adverse events [*sic*] how these old 'side effects' can be turned into 'proprietary new uses'" (App. Br. 16). Appellant does not identify the claim recitations that D'Ambra purportedly fails to teach. The Examiner relies on D'Ambra as teaching "wherein the proprietary method consists of a use selected from the group consisting of a restricted use, providing warnings about the essential adverse event, providing instructions for avoiding an essential adverse event and any combination thereof" (Ans. 7). These limitations do not discuss turning new adverse events into proprietary new uses. Appellant further argues that "D'Ambra never teaches how to patent 'side effects' nor that one should patent 'side effects'" (App. Br. 16). However, Appellant does not identify any claim recitations that require patenting. Therefore, we find no error in the Examiner's reliance on D'Ambra.

Regarding the Examiner's use of Risen to show the obviousness of claim 253, Appellant argues that "[c]ommercialization of an adverse event has to do more than simply placing a warning on a label [*sic*]. One has to obtain specific profit for having it on the label and that value must be generated through a sale, as opposed to use of a product" (App. Br. 19). However, claim 253 merely recites that "the commercializing step further

comprises generating information for incorporation into documents for selling, leasing or licensing the identified product information." Appellant does not show what parts of this recitation require a specific profit or a particular source of value. Therefore, we find no error in the Examiner's reliance on Risen.

Because Appellant relies on limitations that are not supported by claim recitations, we find no evidence persuasive of error in the Examiner's 35 U.S.C. § 103(a) rejection of claims 250 and 253, and claims 251-252 and 254-300 which fall therewith with respect to this issue.

Issue 3

Appellant argues that Stanton does not require identifying a previously unreported adverse event. Based on Appellant's arguments in the Appeal Brief, we will decide the appeal of claims 250-300 with respect to issue 3 on the basis of claim 250. *See* 37 C.F.R. § 41.37(c)(1)(vii).

We are unpersuaded by Appellant's argument that "Stanton fails to make any reference of any kind to an adverse event as being either 'new' or 'essential'" (App. Br. 14). The Specification discloses that "a new essential adverse event can mean a newly discovered adverse reaction such as the discovery of an increased rate of seizures associated with a drug, improved information such as [a] more accurate calculation of the rates of seizures in a group or subgroup" (FF 2). We therefore find that a reasonably broad interpretation, in light of the Specification, of the limitation of a previously unreported (i.e., new) essential adverse event encompass an improved

understanding of whether a group or subgroup faces an increased risk of an adverse event associated with a product or device.

Stanton discloses correlating variances in patient genes with treatment responses (FF 6). In disclosing that "[t]he variances *may* be previously known to exist" (*id.*) (emphasis added), Stanton also discloses or suggests that the variances may be previously unknown. Stanton teaches that this is useful in "demonstrating that a group of patients exists for which the treatment . . . would be . . . contra-indicated" (*id.*). That is, Stanton teaches developing an improved understanding that a group exists which faces an increased risk associated with treatment. Moreover, ADPA discloses adverse event databases (FF 5). Therefore, ADPA and Stanton would have taught or suggested identifying (correlating patient genes) at least one previously unreported (having previously unknown variances) essential adverse event (with adverse event data to demonstrate that a group exists for which treatment would be contra-indicated).

We are also unpersuaded by Appellant's argument that "[w]hat is patentable in Stanton's publication, if anything is patentable, is only the information about the gene variance and the 'old' or 'known' or 'previously reported' adverse event" (App. Br. 15). We look to the what the prior art would have taught or suggested, not what would have been patentable in the prior art.

For at least these reasons, we find no evidence persuasive of error in the Examiner's 35 U.S.C. § 103(a) rejection of claims 250, and claims 251-300 which fall therewith with respect to this issue.

Issue 4

Appellant argues that Rivette does not disclose the claimed database of proprietary essential adverse event data. Based on Appellant's arguments in the Appeal Brief, we will decide the appeal of claims 250-300 with respect to issue 4 on the basis of claim 250. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellant argues that "[w]hile Rivette does mention a patent database, the claim limitation mentions a specific type of patent database" (App. Br. 16). This argument unpersuasively attacks Rivette individually even though the Examiner relies on the combination of ADPA, Stanton, and Rivette as having taught or suggested the claimed database limitation (Ans. 6-7).

Furthermore, ADPA discloses an adverse event database (FF 5), Stanton discloses creating a patient drug response database (FF 7), and Rivette discloses databases of patents (FF 8). Therefore, ADPA, Stanton, Rivette, and D'Ambra would have taught or suggested creating a database (patient drug response database) of proprietary essential adverse event information (used as an adverse event database), wherein the database comprises at least one of: a patent, a patent application, or patent publication (and also including a database of patents).

For at least these reasons, we find no evidence persuasive of error in the Examiner's 35 U.S.C. § 103(a) rejection of claims 250, and claims 251-300 which fall therewith with respect to this issue.

Issue 5

Appellant argues that the Examiner erred in finding that Stanton, Rivette, and D'Ambra would have been combinable. Based on Appellant's arguments in the Appeal Brief, we will decide the appeal of claims 250-300 with respect to issue 5 on the basis of claim 250. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellant submits that "Stanton actually teaches away from Applicant's required 'essential' adverse event, since the term 'essential' as defined by Applicant, *implies* a manufacture must disclose the adverse event information – as opposed to getting government approval . . . before disclosing the information – as taught by Stanton" (App. Br. 16) (emphasis added). This is unpersuasive because a meaning that is merely implied is not sufficiently clear so that an artisan would understand its specialized meaning. Furthermore, the Specification discloses that "a new essential adverse event *can mean* a newly discovered adverse reaction" (FF 2) (emphasis added) and that "[t]he final determination of what is 'essential' is determined by a regulatory agency *such as* the FDA" (FF 3) (emphasis added). The Specification's disclosure of what "essential adverse event" means is therefore very broad, encompassing any adverse reaction that any regulatory agency could define as essential.

Even if we were to read the scope of an essential adverse event narrowly, we would not be persuaded by Appellant's arguments. Stanton merely describes obtaining government regulatory approval as a potential benefit of "demonstrating that a group of patients exists for which [a]

treatment or method of treatment would be particularly beneficial or contra-indicated" (FF 6). Appellant does not show that this disclosure of an example of a potential benefit would have discouraged an artisan from using Stanton's teachings and suggestions for other benefits.

Appellant further argues that "D'Ambrosa actually teaches away from Classen [U.S. Patent Application No. 09/804,289] by teaching to develop new proprietary derivatives of Terfadine rather develop [*sic*] new proprietary uses for Terfadine responsive to identifying new adverse events" (App. Br. 16-17). Appellant submits that Classen "is included by reference and cited in the present application" (App. Br. 14).

We are unpersuaded that differences between Classen and D'Ambra are appurtenant. Classen is merely referenced as part of the invention's background (FF 1). Thus, an artisan would reasonably believe that Classen does not describe the present invention itself. Therefore, the inclusion by reference of Classen does not make any special claim term meaning sufficiently clear.

Even if Classen could impact the scope of the claimed invention, Appellant fails to identify claim language that Classen defines. Therefore, we are not persuaded that D'Ambra teaches away from the claimed invention.

For at least these reasons, we find no evidence persuasive of error in the Examiner's 35 U.S.C. § 103(a) rejection of claims 250, and claims 251-300 which fall therewith with respect to this issue.

Issue 6

Appellant argues that Colombo would not have taught or suggested determining the value of commercializing. Based on Appellant's arguments in the Appeal Brief, we will decide the appeal of claims 251-255, 258, 259, 262, 263, 265, 267, 269, 271, 273, 282, 286, 288-290, and 300 with respect to issue 6 on the basis of claim 251. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellant submits that "the Colombo passage has nothing to do with . . . . determining the 'value of commercialization'" (App. Br. 18). Appellant submits that determining the value of commercialization "is defined in the specification paragraphs 123-127, under the Heading 'Methods of Screening Adverse Events for Commercial Value'" (*id.*). However, Appellant's argument is based on a non-existent disclosure. For example, Appellant submits that the second sentence of paragraph [0124] reads "'*Commercial value*' depends on the potential value of making a generic product or device into a proprietary product or device" (*id.*) (emphasis added). In the Specification, the second sentence of this paragraph actually reads "*Value* depends on the potential value of making a generic product or device into a proprietary product or device" (FF 4) (emphasis added). Because Appellant's argument relies on a faulty presentation of the Specification's disclosure, we are not convinced that the Specification defines "determining the value of commercialization" such that ADPA, Stanton, Rivette, D'Ambra, and Colombo would not have taught or suggested determining the value of commercializing at least one use for a product of manufacture or device.

Even if Appellant has accurately quoted the Specification in its current state, we would not be persuaded of error. The passage Appellant provides discusses "commercial value" and "potential commercial value" (App. Br. 18). However, neither of these terms clearly limits the meaning of "determining the value of commercialization." Colombo teaches using readily available and relatively inexpensive chemical modifiers to develop modified sulfur cement with improved product durability (FF 9). Therefore, ADPA, Stanton, Rivette, D'Ambra, and Colombo would have taught or suggested determining the value (i.e., improved product durability by) of commercializing at least one use (modifying sulfur cement) for a product of manufacture or device (using readily available and relatively inexpensive chemical modifiers).

For at least these reasons, we find no evidence persuasive of error in the Examiner's 35 U.S.C. § 103(a) rejection of claims 251, and claims 252-255, 258, 259, 262, 263, 265, 267, 269, 271, 273, 282, 286, 288-290, and 300 which fall therewith with respect to this issue.

Issue 7

Appellant argues that the Examiner erred by taking official notice of facts. Based on Appellant's arguments in the Appeal Brief, we will decide the appeal of claims 259-269, 271, 277-280, 283, 284, 290, and 291 with respect to issue 7 on the basis of claim 259. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellant submits that "the gaps between the cited art and Applicant's invention are great . . . relying on facts such as: raw commercial or sales

data, proprietary information, medical products, non-medical products, product exposure time, and date of inventorship" (App. Br. 20-21). However, Appellant does not state why Examiner's taking of official notice of the state of the art includes noticed facts not considered to be common knowledge or well-known in the art. Furthermore, Appellant does not demonstrate adequate traversal of the Examiner's taking of official notice during prosecution. Therefore, Appellant does not offer any arguments or evidence to show a basis for appealing the Examiner's taking of official notice.

Appellant further argues that "the facts of which the Examiner has taken Official Notice do not provide one skilled in the art to arrive at Applicant's invention because one would not arrive at a database of 'proprietary essential adverse events' given the additional facts" (App. Br. 21). We find this argument unpersuasive because the Examiner does not rely on the taking of official notice in finding that the prior art would have taught or suggested this limitation. As discussed above, ADPA, Stanton, Rivette, and D'Ambra would have taught or suggested creating a database of proprietary essential adverse event information.

For at least these reasons, we find no evidence persuasive of error in the Examiner's 35 U.S.C. § 103(a) rejection of claim 259, and claims 258-269, 271, 277-280, 283, 284, 290, and 291 which fall therewith with respect to this issue.

Issue 8

Appellant challenges the Examiner's use of Jacob's printed product warning information teachings. Based on Appellant's arguments in the Appeal Brief, we will decide the appeal of claims 299 and 300 with respect to issue 8 on the basis of claim 299. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Appellant argues that "[s]imply placing a warning as does Jacob does not teach creating 'proprietary methods of use wherein the use comprises providing printed product warning information . . .'" (App. Br. 22). This argument unpersuasively attacks Jacob individually, even though the rejection is based on the combined teachings and suggestions of ADPA, Stanton, Rivette, D'Ambra, and Jacob. The Examiner relies on ADPA, Stanton, Rivette, and D'Ambra to show that the claimed proprietary methods of use would have been obvious to an artisan (Ans. 3-7). Jacob teaches a warning on disposable diapers labels regarding the risks associated with release paper strips (FF 10). Appellant has not shown that it would be uniquely challenging or difficult for an artisan to combine the teachings and suggestions of these references. Therefore, we find that ADPA, Stanton, Rivette, D'Ambra, and Jacob would have taught or suggested a proprietary method of use (as taught or suggested by ADPA, Stanton, Rivette, and D'Ambra) comprising providing printed product safety information (a warning) in connection with product packaging (regarding release paper strips).

For at least these reasons, we find no evidence persuasive of error in the Examiner's 35 U.S.C. § 103(a) rejection of claim 299, and claim 300 which falls therewith with respect to this issue.

Issue 9

Appellant submits the sworn declaration of Dr. John B. Classen, the inventor of the present application, as evidence of the invention's patentability. We have reviewed this declaration, along with the attached evidence, but are not persuaded.

As the inventor, Dr. Classen is not a disinterested party. Thus, his opinions are presumed to be mere arguments or conclusory statements, not factual evidence of non-obviousness. *Cf. In re De Blauwe*, 736 F2d at 705.

Even if Dr. Classen's opinions are accepted as factual evidence, the declaration is not persuasive. The declaration purports to show non-obviousness based on interactions between Dr. Classen and Elan Pharmaceuticals (FF 11). Yet, these interactions include a patent infringement suit based on two other patents (FF 12). Dr. Classen also declares that "generic drug competitors have begun copying [his] technique" (FF 13) and that others were skeptical at the time the previously issued patent was filed (FF 14).

Dr. Classen's submissions are not persuasive because the issued patents, and the currently claimed invention, are referenced without distinction. Even if Dr. Classen's existing patents are valid and are being infringed, other applications, even if related, are not automatically patentable. Each patent application must be reviewed on a case-by-case

basis. For example, Dr. Classen's declaration regarding skepticism about whether it is "possible to completely prevent generic drug competition for [an] original formulation . . . after the original patents had expired" in 1999 (FF 14) does not provide convincing evidence that skepticism existed regarding the currently claimed invention in 2001, the priority date for the current application. Because the declaration fails to show how evidence of nonobviousness pertains to the claimed invention, we are not persuaded that secondary considerations demonstrate error in the Examiner's rejection.

For at least these reasons, we find no evidence persuasive of error in the Examiner's 35 U.S.C. § 103(a) rejection of claims 250-300 with respect to this issue.

CONCLUSIONS OF LAW

Based on the findings of facts and analysis above, we find no evidence persuasive:

1. that the Examiner erred in using the Stanton reference in rejecting Appellant's claims (issue 1);

2. that the Examiner erred in finding that the claimed invention does not recite limitations argued by Appellant (issue 2);

3. that the Examiner erred in finding that ADPA, Stanton, Rivette, and D'Ambra would have taught or suggested identifying at least one previously unreported essential adverse event (issue 3);

4. that the Examiner erred in finding that ADPA, Stanton, Rivette, and D'Ambra would have taught or suggested creating a database of proprietary

essential adverse event information, wherein the database comprises at least one of: a patent, a patent application, or patent publication (issue 4);

5. that the Examiner erred in finding that it would have been obvious to an artisan to combine the teachings and suggestions of ADPA, Stanton, Rivette, and D'Ambra (issue 5);

6. that the Examiner erred in finding that ADPA, Stanton, Rivette, D'Ambra, and Colombo would have taught or suggested determining the value of commercializing at least one use for a product of manufacture or device (issue 6);

7. that the Examiner improperly took official notice of the state of the art (issue 7);

8. that the Examiner erred in finding that ADPA, Stanton, Rivette, D'Ambra, and Jacob would have taught or suggested a proprietary method of use comprising providing printed product safety information in connection with product packaging (issue 8); and

9. that secondary considerations of nonobviousness demonstrate that the Examiner erred in finding that the prior art would have taught or suggested the claimed invention (issue 9).

DECISION

We affirm the Examiner's decisions rejecting claims 250-300 under 35 U.S.C. § 103(a).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

msc

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